



Drug Enforcement Administration Pharmaceutical Industry Conference

A Wholesale Distribution Diversion Control Program

October 15, 2009

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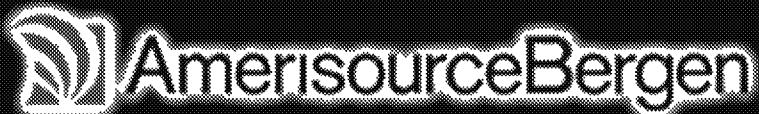
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Regulatory Responsibility

Title 21 of the Code of Federal Regulations:

1301.71(a) - "All applicants and registrants shall provide **effective controls** and procedures to **guard against** theft and **diversion** of controlled substances."

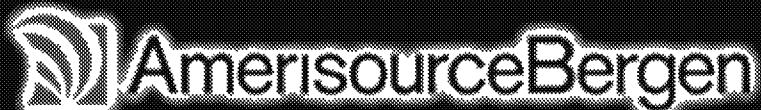
Distributor Response: Develop policy to

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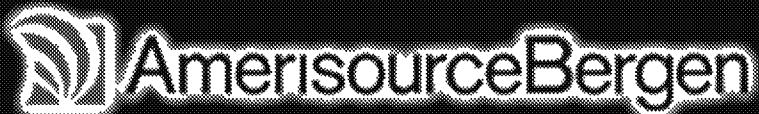
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ABC's Diversion Control Program

- ▶ Prior to June 2007
- ▶ After June 2007
- ▶ September 2007 – ABC Presentation to the
DEA Pharmaceutical Industry Conference,
Houston TX
- ▶ October 2009

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ABC's Diversion Control Program

- ▶ “Know Your Customer” Due Diligence
- ▶ Order Monitoring Program (OMP)
- ▶ Investigations
- ▶ Education and Training

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New Customer Due Diligence

• 2007 – 438

• 2008 – 929

• 2009 – 1,356

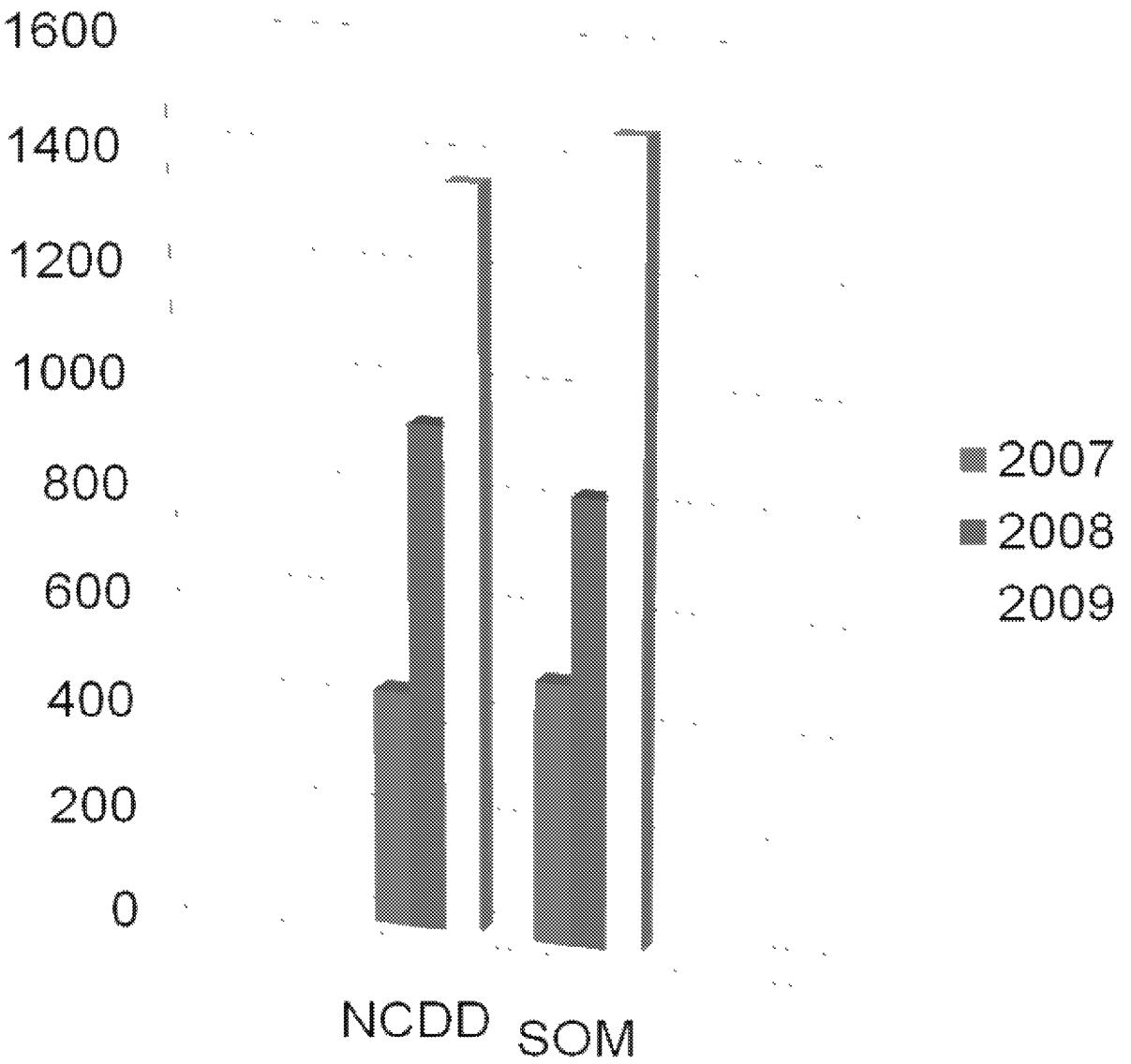
Number includes review of existing customers.

Suspicious Order Monitoring Investigations

• 2007 – 483

• 2008 – 822

• 2009 – 1,453



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Order Lines Reviewed

- 2007 – 40,000

- 2008 – 36,000

- 2009 – 25,686

Suspicious Orders (Lines) Reported

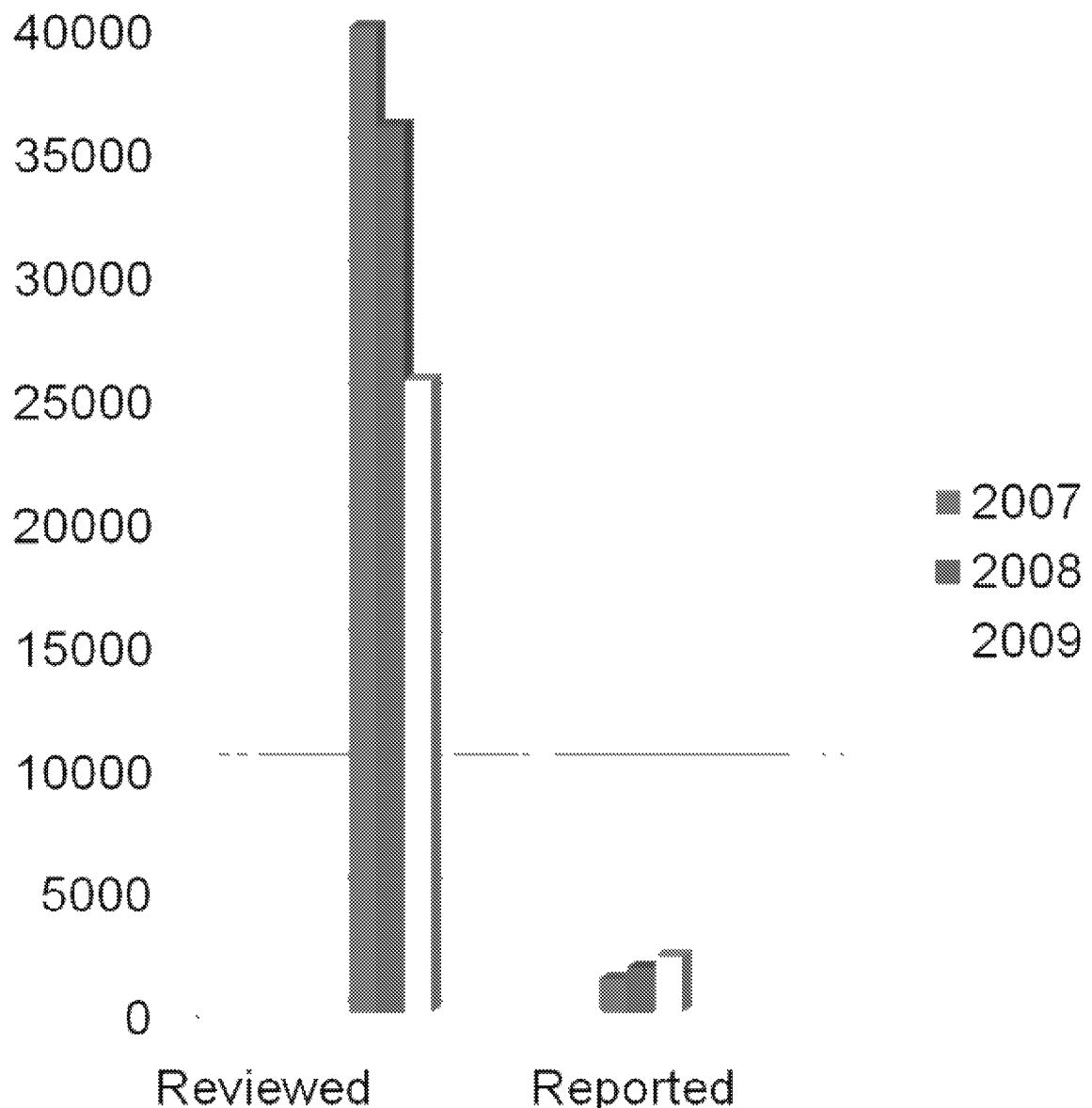
- 2007 – 1,393

- 2008 – 1,858

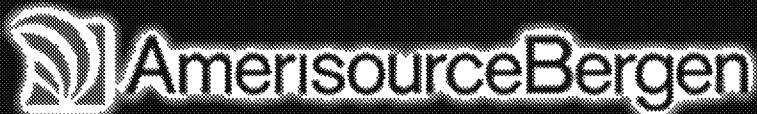
- 2009 – 2,322

Line Items Received

On average ABC processes about 215,000,000 lines per year



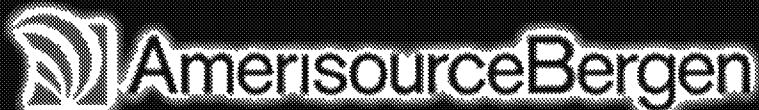
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Internal Departmental Changes

- ▶ A dedicated Diversion Control staff, consisting of a manager, two diversion investigators, and one investigator/analyst was implemented.
- ▶ This staff was given the responsibility for the Order Monitoring Program, Suspicious Order Investigations, New Customer Due Diligence Investigations, targeted pharmacy visits, trending reports, and customer and employee/customer education.
- ▶ On a monthly basis, the diversion control staff reviews about 3,000 orders.
- ▶ Approximately 6% or 180 orders per month are investigated and subsequently reported to the DEA as suspicious orders. These orders are not shipped.

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Diversion Control – An Ever Evolving Program

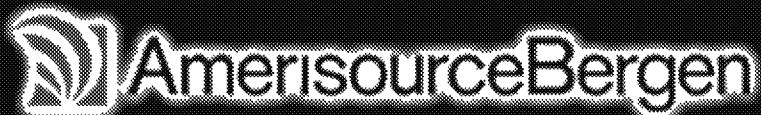
Then

- ▶ No dedicated DC staff
- ▶ 2 page questionnaire
- ▶ Basic due diligence
- ▶ Hydrocodone and Alprazolam
- ▶ Internet sales
- ▶ Limited interaction with pharmacy
- ▶ Few compliance specific visits
- ▶ Limited guidance provided

Now

- ▶ Manager, 2 investigators, analyst
- ▶ 5 page questionnaire
- ▶ Enhanced due diligence
- ▶ High risk CS / Tramadol & Soma
- ▶ Pain Management / Dispensing docs
- ▶ Regular interaction with pharmacy
- ▶ Regular compliance specific visits
- ▶ Model Policies & Procedures

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Questions?

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